DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
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Bothell, WA 98021-4421

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December 3, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-08
Judd A. Pindell, President
Mind's Eye Juice Company
160 Helman Street
Ashland, Oregon 97520

WARNING LETTER

Dear Mr. Pindell:

We inspected your firm, located at 160 Helman Street, Ashland, Oregon, on August 25 and 26, 2004. The inspection was conducted to determine your compliance with FDA's requirements for foods, including food safety (21 U.S.C. § 409), labeling (21 CFR Parts 101 and 102), Hazard Analysis and Critical Control Point (HACCP) systems for juice processing (21 CFR Part 120), and Current Good Manufacturing Practice regulations for foods (21 CFR Part 110). This was a follow-up to the February 2004 inspection. During the inspection, we found that you have serious deviations from the Federal Food, Drug, and Cosmetic Act (the Act) and the regulations. You can find the Act and the regulations through links on FDA's homepage at www.fda.gov.

During the inspection, our investigator found deviations from the juice HACCP regulation with respect to e your unpasteurized 100% orange juice. In accordance with 21 CFR 120.9, the failure of a processor to have and implement a HACCP plan that complies with this section, or to otherwise operate in accordance with the requirements of this Part, renders the juice products to be adulterated within the meaning of Section 402(a)(4) of the Act (21 U.S.C. § 342(a)(4)).

Our investigator also found that your product Zen-Mind is adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. § 342(a)(2)(C)) in that it bears or contains an unsafe food additive, Kava Kava (*Piper methysticum*), also known as kava.

Finally, our investigator found that the following products are improperly labeled in violation of section 403 of the Act (21 U.S.C. § 343):

- Zen-Mind Orange-Strawberry-Kiwi Herbal Supplement with Kava Kava & Passion Flower (Zen-Mind);
- Electro-Mind Orange-Blueberry Juice Herbal Supplement with Yerba Mate & Electrolytes (Electro-Mind);

- Clear-Mind Orange-Pineapple Herbal Supplement with Ginkgo Biloba & DMAE (Clear-Mind); and
- Super Green Juice Fortified with Klamath Lake Blue Green Algae (Super Green Juice).

Although your products, Zen-Mind, Electro-Mind, and Clear-Mind, are labeled as dietary supplements, they do not meet the definition of a dietary supplement under the Act. Section 201 (ff)(2)(B) of the Act (21 U.S.C. § 321 (ff)(2)(B)) defines the term "dietary supplement" to exclude products represented for use as conventional foods. Zen-Mind, Electro-Mind, and Clear-Mind are represented as conventional foods through statements and vignettes on the product labels. For example, the product labels state "[f]resh juice for a thirsty planet" and "fresh, tasty juices," which represent these products to be conventional foods. In addition, the products bear vignettes of fruit and contain nutrition facts panels, providing further evidence that they are represented as conventional foods. Despite the nominal use of the words "Herbal Supplement," it is clear that the products are represented as juices, which are conventional foods. Because your products are conventional foods, namely beverages, the products are violative as follows.

Food Additives

Your product Zen-Mind is adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. § 342(a)(2)(C)) in that it bears or contains an unsafe food additive, Kava Kava (*Piper methysticum*), also known as kava.

Kava was the subject of a public health advisory issued by FDA on March 25, 2002, which advised consumers of the risk of liver damage resulting from the use of kava. Regulatory authorities in several other countries have also taken action regarding kava, ranging from warning consumers about the potential risks of kava use to removing kava-containing products from the marketplace. The American Herbal Products Association also recently adopted new cautionary language to appear on the label of kava-containing products. These actions have been prompted by recent reports associating the use of kava-containing products with serious liver injury.

Under the Act, any substance intentionally added to a conventional food, such as a beverage product, must be used in accordance with a food additive regulation approving the substance for that use, unless the substance is generally recognized as safe (GRAS) among qualified experts for its intended use in foods, or is otherwise exempt from the food additive definition in section 201(s) of the Act. We are unaware of any basis to conclude that kava is the subject of a prior sanction or is GRAS for use in beverages, nor is FDA aware of any other exemption from the food additive definition that would apply to kava for use as an ingredient in beverages. Therefore, kava used in this manner is a food additive under section 201(s) of the Act and is subject to the provisions of section 409 of the Act. Under section 409, a food additive is required to be approved by FDA for its intended use prior to marketing. Kava is not an approved food additive for use in beverages. Therefore, your product Zen-Mind, a beverage containing kava, is adulterated under section 402(a)(2)(C) of the Act.

Labeling

Super Green Juice Fortified with Klamath Lake Blue Green Algae (Super Green Juice)

Your product is misbranded under section 403(i)(1) of the Act (21 U.S.C. § 341(i)(1) in that the label fails to bear a common or usual name that accurately identifies or describes a beverage that contains fruit or vegetable juice, as also required by 21 CFR 102.33(a). For example, the product is labeled as being composed of 92% juice; however, the product name does not include a qualifying term, such as "diluted" or "juice drink," to advise consumers that the products is not 100 percent juice, as required by 21 CFR 102.33(a). In addition, the primary juice ingredient in the product is pineapple juice from concentrate, but the product name does not indicate that fact, as required by 21 CFR 102.33(g)(1).

Your product is further misbranded under section 403(r)(1) of the Act (21 U.S.C. § 343(r)(1)) in that the statement on the label "Fortified with KLAMATCH LAKE BLUE GREEN ALGAE" does not comply with the definition for use of the claim "fortified." The term "fortified" has been defined by regulation to be a synonym for the claim "more" and may only be used to describe the level of protein, vitamins, minerals, dietary fiber, or potassium. *See* 21 CFR 101.54(e). Because Klamath Lake blue-green algae is not one of the listed nutrients, the claim on your product is unauthorized. Therefore, the claim may not appear on the label of the product.

Electro-Mind Orange-Blueberry Juice Herbal Supplement with Yerba Mate & Electrolytes (Electro-Mind)

Your product is misbranded under section 403(u) of the Act (21 U.S.C. § 343(u)) in that the ingredient statement bears the ingredient "Siberian Ginseng" which is not derived from the plant classified within the genus Panax. Section 403(u) of the Act, added by the Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171), provides that the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus *Panax*. Siberian Ginseng (*Eleutherococcus senticosus*) is not a member of the Panax genus.

Your product is further misbranded under section 403(i)(1) of the Act (21 U.S.C. § 343(i)(1)) in that the label fails to bear a common or usual name that accurately identifies or describes a beverage that contains fruit or vegetable juice. For example, the name of the product does not indicate that the orange and blueberry juices are from concentrate as required by 21 CFR 102.33(g)(1).

Moreover, your product is also misbranded under section 403(i)(2) of the Act (21 U.S.C. § 343(i)(2)) in that it is a food that contains juice, but the label fails to bear a statement on the information panel of the total percentage of juice contained in the food, as also required by 21 CFR 101.30(a).

Zen-Mind Orange-Strawberry-Kiwi Herbal Supplement with Kava Kava & Passion Flower (Zen-Mind)

Your product is misbranded under section 403(i)(1) of the Act (21 U.S.C. § 343(i)(1)) in that the label fails to bear a common or usual name that accurately identifies or describes a beverage that contains fruit or vegetable juice. For example, the product name on the principal display panel does not identify the product as either a juice or juice beverage. The product name also fails to indicate that kiwi is present only as a flavor as required by 21 CFR 102.33(d)(1). In addition, the name of the product fails to indicate that the orange juice is from concentrate as required by 21 CFR 102.33(g)(1). We also note that the side panel identifies the product as "Zen-Mind Orange-Strawberry Juice with Kava Kava & Passion Flower" but fails to indicate that the product also contains kiwi flavor.

Your product is further misbranded under section 403(i)(2) of the Act (21 U.S.C. § 343(i)(2)) in that it is a food that contains juice, but the label fails to bear a statement on the information panel of the total percentage of juice contained in the food, as required by 21 CFR 101.30(a).

Clear-Mind Orange-Pineapple Herbal Supplement with Ginkgo Biloba & DMAE (Clear-Mind)

Your product is misbranded under section 403(i)(1) of the Act (21 U.S.C. § 343(i)(1))in that the label fails to bear a common or usual name that accurately identifies or describes a beverage that contains fruit or vegetable juice. For example, the product name on the principal display panel does not identify the product as either a juice or juice beverage. In addition, the name of the product fails to indicate that the named juices are from concentrate, as required by 21 CFR 102.33(g)(1).

Your product is further misbranded under section 403(i)(2) of the Act (21 U.S.C. § 343(i)(2))in that it is a food that contains juice, but the label fails to bear a statement on the information panel of the total percentage of juice contained in the food, as required by 21 CFR 101.30(a).

Juice HACCP

Your unpasteurized 100% orange juice is adulterated under section 402(a)(4) (21 U.S.C. § 342(a)(4)) of the Act in that you are not operating in compliance with the requirements of 21 CFR Part 120. You must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 120.8(a). However, your firm does not have a HACCP plan for unpasteurized 100% orange juice to control the food safety hazards of pathogens, specifically *Salmonella.* Furthermore, your firm does not have a written hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and to identify control measures that you can apply to control those hazards for the unpasteurized 100% orange juice you process, as required by 21 CFR 120.7.

We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your products and/or enjoin your firm from operating.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. We encourage you to make the necessary improvements as soon as possible. This letter is not intended to be a complete review of all the substances in your products. You should review the ingredients in your products to ensure that they may be used in food products.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation [e.g. labeling, HACCP plans, monitoring records] or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any question regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4813.

Sincerely,

Charles M. Breen
District Director

Enclosures:
Section 402 and 403 of the FD&CAct

cc: OSDA with disclosure statement